PATENTS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE -

In re

Claude RANOUX

Patent No. 5,084,004 (Serial No. 07/449,942)

Expired January 28, 1996 (Filed December 29, 1989) Issued January 28, 1992

PROCESS FOR INTRA-UTERINE FERTILIZATION IN MAMMALS AND DEVICE FOR IMPLEMENTATION THEREOF

PETITION TO ACCEPT UNAVOIDABLE CENTREMENTS

OF MAINTENANCE FEE IN AN EXPERIENT UNDER 37 C.F.R. \$1.378(b)

nt Commissioner for Paton

FEB 1 8 2000

Assistant Commissioner for Patents

Washington, D.C. 20231

Sir:

respectfully requested that the delayed Ιt payment of the first maintenance fee for U.S. patent No. 5,084,004 (the '004 patent) be accepted, and the patent be reinstated.

Petitioner hereby states that the entire delay in payment of the first maintenance fee for U.S. patent No. 5,084,004 was unavoidable.

The present delay in payment was unavoidable as the patent owner's representatives exercised reasonable care to ensure that the maintenance fee would be padd timely and the present petition was filed promptly after the patentee was notified of expiration of the '004 patent

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Patent No. 5,084,004

It is respectfully submitted that the requirements of 37 C.F.R. § 1.378(b) have been complied with and it is petitioned that the delayed payment of the first maintenance fee be accepted, and that the patent be reinstated.

Should the accompanying check be found to be insufficient, the Commissioner is hereby authorized to charge any deficiency, including the second maintenance fee payment, to counsel's Deposit Account No. 25-0120. Similarly, the Commissioner is also authorized to credit counsel's Deposit Account No. 25-0120 any overpayment.



Respectfully submitted,

YOUNG & THOMPSON

R

Eric Jensen

Attorney for Patentee Registration No. 37,855 745 South 23rd Street Arlington, VA 22202 Telephone: 521-2297

February 18, 2000

Patent No. 5,084,004 P E 705 THE 18 2000 THE

Background

The Declaration of Robert J. Patch is included as Exhibit A and is incorporated herein by reference. The patent owner was represented by two separate law firms in the prosecution of Application Serial No. 08/449,942 (the '942 application), which matured into the '004 patent. Petition-er's law firm of Young & Thompson represented the applicant before the USPTO, but Young & Thompson did not receive instructions directly from the applicant. Instead, Young & Thompson reported to and received instructions from the applicant's representative in France, the law firm of Cabinet Bonnet-Thirion.

While the application was pending, Robert Patch of Young & Thompson received a telephone call from Examiner Reichle, the Examiner in charge of the '942 application. Examiner Reichle recommended claim amendments which would, in her opinion, place the application in condition for allowance. Because of a misunderstanding between Mr. Patch and Examiner Reichle as to the nature of the proposed amendment, Mr. Patch agreed to the changes, which were later determined to be inappropriate.

Young & Thompson reported the subsequently issued Notice of Allowability of August 6, 1991 with a copy of the Examiner's Amendment to Cabinet Bonnet-Thirion. Mr. Herbert Lewitter of Cabinet Bonnet-Thirion reviewed the Examiner's Amendment and discovered the impropriety thereof. On September 11, 1991, Mr. Patch filed an amendment under Rule 312 to

correct the claims. The amendment under Rule 312 was not acted upon until over four months later, on January 14, 1992. Shortly thereafter the patent issued, on January 28, 1992.

The only recourse available to the applicant at this point was a broadening reissue application. Young & Thompson did not send to Cabinet Bonnet-Thirion the original Letters Patent No. 5,084,004 upon receipt of the same, as it was clear that it was only going to be sent back to the U.S. Patent Office with the reissue application. Young & Thompson did so include the original Letters Patent with the reissue application filed June 15, 1992. See Exhibit B, copy of stamped receipt card indicating receipt of original Letters Patent by PTO with reissue application.

At the time of the issue of the '004 patent, Cabinet Bonnet-Thirion used Young & Thompson for payment of maintenance fees for patents obtained through Young & Thompson, but Cabinet Bonnet-Thirion instructed Young & Thompson on February 5, 1994 to discontinue docketing cases prosecuted for Cabinet Bonnet-Thirion, and to file a Fee Address Indication Form with the USPTO identifying Accumas Computer Packages Annuity Service for such patents. See Exhibit C, copy of telefax of February 5, 1994. Young & Thompson complied with this request and filed such form with the USPTO in connection with the '004 patent on March 17, 1995. See Exhibit D, copy of Fee Address Update form. The time period for payment of the first maintenance fee for the '004 patent without surcharge was between January 28, 1995 and July 28, 1995.

The first indication that maintenance fees had not been paid for the '004 patent came in the form of a telephone call to Young & Thompson from Examiner Reichle, who is also in charge of the reissue application, on December 21, 1999, just prior to the Christmas and New Year holidays. Exhibit E, declaration of Eric Jensen. It appears that the Examiner had just checked for the first time whether the maintenance fees had been paid. According to the online records of the USPTO, neither the first nor the second maintenance fee installments had been paid for the '004 patent.

After receipt of this call, both Young & Thompson and Cabinet Bonnet-Thirion checked their respective records to determine whether this information was accurate. After reconstructing the unusual chain of events in this case, the two firms immediately took the steps necessary to prepare and file the present petition.

Steps taken to ensure timely payment of the maintenance fee

Young & Thompson provides maintenance fee payment services for some of its clients. To ensure reliable payment of such fees, Young & Thompson has implemented a procedure which includes both a computer docketing system and data books with manually entered information. Through utilization of such a system, maintenance fee payment information for a particular patent would have to be missing from both data sets for the payment to be missed. As discussed above, however, Young & Thompson was instructed by Cabinet Bonnet-Thirion

prior to the due date of the first maintenance fee payment for the '004 patent to discontinue docketing of Cabinet Bonnet-Thirion's cases.

Cabinet Bonnet-Thirion has its own docketing system described in Exhibit G, the entirety of which is incorporated herein by reference.

For the reasons discussed below, a highly unusual and perhaps even unique set of circumstances resulted in thwarting the very rigorous procedures put in place by both of the law firms involved with the '004 patent.

The date and manner in which the patentee became aware of the expiration of the patent

As discussed *supra* in the Background section of this petition, the first indication of the expiration of the '004 patent was a telephone call to Young & Thompson from the Examiner in charge of the reissue application on December 21, 1999.

Steps taken to file the present petition promptly

Upon receiving the above-described telephone call four days before Christmas, the information was passed to Mr. Lewitter of Cabinet Bonnet-Thirion. The two law firms checked their respective records to determine whether the fees had been paid. Upon discovering that the fees had not been paid, the two firms further investigated to determine how this had

Patent No. 5,084,004

happened, all of which was necessary prior to preparation and filing of the present petition.

Discussion

As stated in Ray v. Lehman,:

A late maintenance fee is considered under the same standard as that for reviving an abandoned application under 35 USC 133 because 35 USC 41(c)(1) uses the identical language, i.e., unavoidable delay. Decisions on reviving abandoned applications have adopted the "reasonably prudent person" standard . . . In addition, decisions on revival are made on a "case-by-case basis, taking all the facts and circumstances into account."

34 USPQ2d 1786, 1787 (Fed. Cir. 1995) (quoting In re Patent No. 4,461,759, 16 USPQ2d 1883, 1884 (Dep. Ass't Comm'r Pat. 1990)). "Thus, in determining whether a delay in paying a maintenance fee was unavoidable, one looks to whether the party responsible for payment of the maintenance fee exercised the due care of a reasonably prudent person." Id. Petitioner believes it is clear from the facts of the present case that such care was exercised.

As discussed above, both Young & Thompson and Cabinet Bonnet-Thirion have time-tested procedures in place to ensure timely payment of maintenance fees on behalf of their

clients. The '004 patent escaped detection by both of these systems because of a highly unusual set of circumstances.

Because of the misunderstanding between Mr. Patch and the Examiner and the subsequent issue of the '004 patent after the USPTO failed to act on the timely filed amendment under Rule 312, the '004 patent was known to be flawed at the time of issue. As a consequence, Cabinet Bonnet-Thirion received neither the original Letters Patent for the '004 patent nor the form letter from Young & Thompson which normally accompanies such, as the Letters Patent was submitted with the reissue application.

The maintenance fee payment agreement between Cabinet Bonnet-Thirion and Young & Thompson in place at the time of issue of the '004 patent was sufficient to properly handle the facts as they existed at the time of issue, as Young & Thompson's docketing system was set to provide the necessary reminders for this patent.

However, prior to the payment of the first maintenance fee for the '004 patent, Cabinet Bonnet-Thirion instructed Young & Thompson to discontinue docketing Cabinet Bonnet-Thirion's cases with respect to maintenance fees. Cabinet Bonnet-Thirion quite reasonably had put in place a docketing system which was triggered by receipt of the original Letters Patent and accompanying form letters received from Young & Thompson. The original Letters Patent was not sent to Cabinet Bonnet-Thirion because of the need to immediately file the reissue application, and the Young & Thompson

docket system was cleared of the necessary maintenance fee payment information because of the change in procedure instituted by Cabinet Bonnet-Thirion subsequent to the issue of the '004 patent and prior to the due date of the first maintenance fee payment. Only because of these highly unusual circumstances, the docket systems of neither Young & Thompson nor Cabinet Bonnet-Thirion indicated the need to pay the first maintenance fee when it was due.

Contributing to the failure to pay maintenance fees with respect to the present patent is the silence on this subject from the Examiner in charge of the reissue application. According to MPEP §1415.01, which addresses the payment of maintenance fees on a patent for which reissue is sought, an Examiner should determine whether all required maintenance fees have been paid prior to conducting an examination of a reissue application. Failure to pay the necessary maintenance fees by the fourth, eighth, and twelfth anniversary dates should result in a rejection under 35 USC §251. present case, after the fourth anniversary of January 28, 1996, the Examiner in charge of the reissue application examined the application to prepare and file an Examiner's Answer, mailed May 21, 1996; a communication from the Examiner mailed September 4, 1996; an Official Action mailed August 13, 1998; an Official Action mailed March 11, 1999; an Official Action mailed April 26, 1999; and an Official Action mailed November 16, 1999. None of these communications from the Examiner made any reference to the failure to pay maintenance

fees. See Exhibit F, copies of the above-mentioned communications from Examiner Reichle.

As stated in the MPEP, prior to examining the reissue application in connection with each of these actions taken by the Examiner, she should have checked the Patent Office records to determine whether the maintenance fees due at that point had been paid. This was clearly not the case, as the first indication the patent owner had that maintenance fees had not been paid came in the form of a telephone call from the Examiner on December 21, 1999. It appears that just prior to such call the Examiner had for the first time checked to determine whether the maintenance fees had been paid. After receipt of this call, the patent owner's U.S. and French counsel checked their respective records to determine whether the maintenance fees had been paid. After reconstructing the highly unusual chain of events in this case, the French and U.S. counsel immediately took the steps necessary to file the present petition.

In each case for which the maintenance fee is not paid during the period when such fee may be paid without surcharge, it is the regular practice of the USPTO to mail a Maintenance Fee Reminder. Such Reminder is mailed during the six-month grace period for payment of such fee. It is the further practice of USPTO to mail a Notice of Patent Expiration following the close of the grace period.

In the present case, Cabinet Bonnet-Thirion instructed Young & Thompson on February 5, 1994 to discontinue docketing cases prosecuted for Cabinet Bonnet-Thirion, and to file a Fee Address Indication Form with the USPTO identifying Accumas. Young & Thompson filed such form with the USPTO on March 17, 1995. Such filing antedates by several months the deadline for paying the first maintenance fee without surcharge (July 28, 1995) and the expiration date (January 28, 1996). If a Reminder and Notice were sent with respect to the '004 patent, they would have been sent to the fee address of record, namely Accumas. However, because Accumas received no indication from Cabinet Bonnet-Thirion that fees were to be paid for this patent, and Accumas would have no way of connecting this patent to its client Cabinet Bonnet-Thirion, Accumas clearly had no indication that it was to pay fees for this patent.

Furthermore, even given the set of circumstances discussed above, notice of the need to pay the first maintenance fee would have arisen had the present reissue application issued during a reasonable period from the time of filing. For instance, had the reissue application issued three years after its filing date (surely a realistic expectation), the issue of such would have triggered the docketing system of Cabinet Bonnet-Thirion and the maintenance fee could have been paid prior to the fourth anniversary of the issue of the '004 patent, thereby avoiding expiration of such patent.

As is evident from this chain of events, it is only because the '004 patent issued in a flawed state because of failure of the PTO to act on a timely filed Rule 312 amendment

resulting in the issuance of a known flawed patent and the original Letters Patent was never sent to Cabinet Bonnet-Thirion because of the need to immediately file a reissue application and Cabinet Bonnet-Thirion changed its maintenance fee payment procedure subsequent to issue of the '004 patent and prior to the due date for the first maintenance fee payment and the Examiner in charge of the reissue application failed to properly issue a rejection based on failure by the reissue applicant to pay maintenance fees on the patent for which reissue was being sought, that the maintenance fees were not paid in this case. Were any one of these events removed from the chain, the maintenance fees would have been timely paid or paid with only a surcharge or petition fee as unintentional.

Based on the facts presented above, Petitioner firmly believes that all parties representing the owner of the '004 patent exercised the due care of a reasonably prudent person with respect to this matter.

Petitioner freely acknowledges that limitations must be placed on the ability of patent owners to pay maintenance fees after their initial due date. Absent any limitations on late payment whatsoever, an unscrupulous patentee would never pay maintenance fees until such time that the patent was deemed to have commercial value. Under such a scenario, all benefits would inure to the patentee, depriving the Patent Office of needed fee income.

There can be no question of the patent owner's motivations in the present case, however. The owner of the '004 patent has, through its French and U.S. counsel, aggressively pursued a reissue of such patent. The reissue application was filed June 15, 1992, and such application has been prosecuted since such date, including an appeal to the Board of Patent Appeals and Interferences resulting in a remand to the Examiner in charge of the case. The patent owner clearly has a strong interest in preventing the patent from expiring, and it is only the unavoidability of the failure to timely pay the maintenance fee which prevented it from doing so.

The granting of the present petition would not be detrimental to the public at large. The Official Gazette published by the USPTO contains in each issue a list of patents which have expired for failure to pay maintenance fees. However, the public cannot rely on such information as a guarantee that the expiration of all patents so listed will remain if effect, as the 35 USC § 41 and 37 CFR § 1.378 provide for late payment of maintenance fees under conditions of unintentional and unavoidable failure to pay. Moreover, there is no time limit for filing a petition under 37 CFR § 1.378(b), such as the present petition.

Furthermore, to take into account the publication in the Official Gazette of the failure to timely pay maintenance fees, one must further take into account the notice in the same publication of the filing of reissue applications, including the reissue application filed with respect to the patent that is the subject of this petition. Presumably, a member of the public would know to further investigate the status of a patent identified as expired knowing that a reissue application had been filed with respect to such application.

A further assurance that the public would not be harmed by the granting of this petition is provided by 35 USC §41(c)(2). This subsection provides protection for parties who practiced that which is claimed in the patent after the 6-month grace period and before acceptance of maintenance fees under the present petition. Such party will even have rights to continue practicing the subject of the patent if equity requires such.

Conclusion

It is only because of a highly unusual and perhaps even unique set of circumstances that the maintenance fees were not paid in this case. All parties representing the patent owner exercised the due care of a reasonably prudent person by putting the proper procedures in place to ensure that the maintenance fees for this and all other patents obtained on behalf of their clients are timely paid. The public would not be prejudiced by the granting of this petition to allow the maintenance fees for this patent to be paid.

Patent No. 5,084,004

It is respectfully submitted that the requirements of 37 C.F.R. § 1.378(b) have been complied with and it is petitioned that the delayed payment of the first maintenance fee be accepted, and that the patent be reinstated.

Should the accompanying check be found to be insufficient, the Commissioner is hereby authorized to charge any deficiency, including the second maintenance fee payment, to counsel's Deposit Account No. 25-0120. Similarly, the Commissioner is also authorized to credit counsel's Deposit Account No. 25-0120 any overpayment.

Respectfully submitted,
YOUNG & THOMPSON

Βv

Eric Jensen

Attorney for Patentee Registration No. 37,855 745 South 23rd Street Arlington, VA 22202 Telephone: 521-2297

February 18, 2000

EXHIBIT A



PATENTS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re

Claude RANOUX

Patent No. 5,084,004 (Serial No. 07/449,942)

Expired January 28, 1996 (Filed December 29, 1989) Issued January 28, 1992

PROCESS FOR INTRA-UTERINE FERTILIZATION IN MAMMALS AND DEVICE FOR IMPLEMENTATION THEREOF

DECLARATION OF ROBERT J. PATCH

Assistant Commissioner for Patents

Washington, D.C. 20231

Sir:

- I, Robert J. Patch, declare as follows:
- 1. I am attorney of record in the above-identified application and patent.
- 2. As such, I do not deal directly with the inventor in respect to this application, but rather with the inventor's patent agency in Paris, France, Messrs. Bonnet-Thirion, and more particularly Mr. Herbert A. Lewitter of that firm.
- 3. On July 31, 1991, I received a telephone call from the Examiner who has charge of this application. The Examiner had recognized patentable subject matter and suggested a number of changes in the claims which would, in the Examiner's opinion, place them in condition for allowance.

- 4. Among the changes proposed by the Examiner were changes to independent claims 28, 50 and 64 which, I now see, would have the effect of limiting the claims such that they would not be infringed if the container were removed from the uterus and then replaced in the uterus, between fertilization and transfer of the fertilized ovocytes to the uterus.
- 5. In the course of that telephone discussion, however, I understood the effect of the changes to be such that the claims would specify that the ovocytes were not to be removed from the container between fertilization and transfer to the uterus. I understood the point of the invention to be that the ovocytes remained in the container throughout, and were directly transferred from the container to the uterus after fertilization, without, as in the prior art, removing the ovocytes from the container in which they had been fertilized and then implanting the removed ovocytes in the uterus. Thus, I thought the Examiner was proposing language that would make more specific what I understood to be the point of the invention; and as a result, I approved the Examiner's telephoned proposals.
- 6. Had I been aware of the actual import of the proposals, I never would have approved them. Specifically, I never would have approved limiting the claims so that they could be avoided simply by removing the container from the uterus and reinserting it in the uterus, which step would have no bearing on the practice of the invention.

Patent No. 5,084,004

- 7. My failure to appreciate the true import of the changes proposed telephonically by the Examiner was error, and it was committed by me without deceptive intent.
- 8. On August 6, 1991, Notice of Allowability was sent to my firm, Young & Thompson, with a copy of the Examiner's Amendment. Again, I did not detect the actual import of the language chosen by the Examiner and did not detect the discrepancy between the actual import and my understanding of it as set forth above.
- 9. On August 21, 1991, Young & Thompson sent to Bonnet-Thirion the Notice of Allowance and the Examiner's Amendment, requesting instructions as to the payment of the issue fee.
- 10. At Bonnet-Thirion, Mr. Lewitter detected my error and wrote a letter of August 30, 1991, pointing it out and asking what could be done.
- 11. On August 30, 1991, I replied by letter stating that an amendment could be filed, and asking for a draft from Bonnet-Thirion of such an amendment.
- 12. On September 3, 1991, Mr. Lewitter wrote, pointing out the error in even greater detail and proposing the necessary changes in claims 28, 50 and 64.
- 13. On September 11, 1991, I prepared and filed an Amendment under Rule 312, seeking to make those changes.
- 14. The Rule 312 amendment was not acted on until January 14, 1992, and the patent issued January 28, 1992,

Patent No. 5,084,004

whereupon a broadened reissue application became the only remedy, and I so notified Bonnet-Thirion.

And I further declare that all statements made herein of ny own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

> MMMM Robert J. Patch

Date February 18, 2000

EXHIBIT B

6/15/92

ATTACHED IS A _____new reissue

PATENT APPLICATION.

07/898407

INVENTOR/S: Claude RANOUX

TITLE: PROCESS FOR INTRA-UTERINE FERTILIZATION

IN MAMMALS AND DEVICE FOR IMPLEMENTATION

THEREOF

CONSISTING OF:

14 PAGES SPECIFICATION

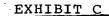
23 CLAIMS

2 SHEETS DRAWINGS (informal)

YES DECLARATION

X Letters Pat. No. 5,084,004; request for title report; request for transfer of drawings; priority claim. PLEASE INDICATE SERIAL NUMBER AND FILING DATE AT RIGHT.

EXHIBIT C



94 TUE 06:52 ID:YOUNG & THOTPSON

#545 P01

YOUNG 8 THOMPSON e SOUTH BEEN STREET (703) BANKERT rassiginaisee sains

ATRIBITA

KOL KOTETODISCE TEES

We refer to your many letters instructing us that ours maintenance has of the above case will be handled an alternative Agency".

Please lat us know whether we are to discontinue your cases and in whose name the "Pee Address" From is to be made out.

Very truly yours.

Paris February 8, 1994

We confirm you are to discontinue dockating your cases. The fee address indication form is to be made out under the name of Atcumes Computer Packages Annuity Service. payor number 000337. Regards .

March 8, 1994

To: Cabinet Bonnet-Thirion

Please fax us the complete address of Accumas Computer Packages Annuity Service.

414 Hungerford Drive ROCKVILLE MARYLAND 20850

Very truly yours

D Young & Thompson

33142780300

BONNET THIRION

1994-03-08 13:54

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Representatives before the E.P.O.)

- A.I.P.P.I.

- L.E.S.

space technics) Facility clearance TRADE MARKS, DESIGNS - Assignment, licence; tranchising agreements

- Technical watch services

- Trademark watch services

EXHIBIT D

"FEE ADDRESS" INDICATION FORM

Address to: Commissioner of Patents & Trademarks Box M. Fee Washington, D.C. 20231

Please recognize as the "Fee Address" under the provisions of 37 CFR 1.363 the following address:

Accumas Computer Packages Annuity Services 414 Hungerford Drive Rockville, MD 20850



Payor Number if assigned

in the following listed application(s) or patent(s) for which the Issue Fee has been paid.

PATENT NUMBER (if known)	SERIAL NUMBER	PATENT DATE (if known)	U.S. FILING DATE
5,084,004	449,942	January 28, 1992	December 29, 1989
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Robert J. Patch Attorney of Record Registration No. 17,355

March 17, 1995

RECEIP	AMP OF T OF THE CH STAN	THE PATENT OFFICE MAIL HEREON ACK E BELOW-IDENTIFIED DOCUMENT ON THE MP.	NOWLEDGES THE DATE INDICATED
In re:	U.S.	Patent No. 5,084,004	<u> </u>

"FEE ADDRESS" INDICATION FORM

4 MAR. 1995

BOX M. FEE

the following address:

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in the following listed application(s) or patent(s) for which the Issue Fee has been paid.

PATENT NUMBER (if known)	SERIAL NUMBER	PATENT DATE (if known)	U.S. FILING DATE
5 004 004	140.040	T 20 1000	December 20 1000
5,084,004	449,942	January 28, 1992	December 29, 1989

Robert J. Patch Attorney of Record Registration No. 17,355

March 17, 1995

EXHIBIT E

EXHIBIT E

PATENTS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re

Claude RANOUX

Patent No. 5,084,004 (Serial No. 07/449,942)

Expired January 28, 1996 (Filed December 29, 1989) Issued January 28, 1992

PROCESS FOR INTRA-UTERINE FERTILIZATION IN MAMMALS AND DEVICE FOR IMPLEMENTATION THEREOF

DECLARATION OF ERIC JENSEN

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

I, ERIC JENSEN, declare that I am an attorney with the law firm of Young & Thompson and that I received a telephone call from Examiner Reichle on December 21, 1999 in connection with reissue application Serial No. 08/128,682, during which call Examiner Reichle stated that she had discovered that the records of the U.S. Patent and Trademark Office indicated that none of the maintenance fees had been paid for U.S. Patent No. 5,084,004;

I further declare that to the best of my knowledge, this is the first indication that Young & Thompson had that the maintenance fees had not been paid with respect to this patent;

I further declare that the law firm of Young & Thompson has in place a procedure for the docketing of maintenance fee payments which includes both a computer docketing system and manually entered data in bound volumes, and that these procedures were in place at the time of the issuance of U.S. Patent No. 5,084,004.

And I further declare that all statements made herein of ny own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Eric Jensen

February 18, 2000

EXHIBIT F

EXHIBIT F



UNITED STATES DEPARTMENT OF COMMERCE Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
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ROBBERT J. PATCH YOURG AND THOMPSON 745 GOUTH J. HAD JURISHY ARLINGTON, VA 25,702 J. F. J. E. V. R. ART UNIT PAPER NUMBER

0308

DATE MAILED:

MAY 2 2-1996

05/21/96

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER OF
PATENTS AND TRADEMARKS
Washington, D.C. 20231

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 28

Serial Number: 128,682 Filing Date: 09/30/93

Appellant(s): CLAUDE RANOUX

MAILED

ROBERT J. PATCH For Appellant

MAY 2 1 1996

GROUP 330

EXAMINER'S ANSWER

This is in response to appellant's brief on appeal filed 2/15/96.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is incorrect. A correct statement of the status of the claims is as follows:

Serial No. 128,682 Art Unit 3308

Appellant does not specify the claims by number.

This appeal involves claims 1-36.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

It is noted, however, declarations were filed after FINAL, see Paper No. 24, but such were not considered for the reasons set forth in Paper No. 25. As discussed in further detail in Section (6) <u>Issues</u>, infra, the issue of the suitability of such nonconsidered declarations filed after FINAL is beyond the scope of this appeal.

(5) Summary of Invention

The summary of invention contained in the brief is deficient because 1) the requirement that there be page and line number references and if there is a drawing, to the drawing if applicable, and 2) the scope of the summary, the last paragraph, one of the bases of contention, is not commensurate in scope with the patent 5,084,004.

A correct summary can be found at col. 1, line 7 - col. 2, line 9 and col. 2, line 62 - col. 3, line 8 of the patent, 5,084,004.

(6) Issues

The appellant's statement of the issues in the brief is substantially correct. The changes are as follows:

1) The only issue in this appeal is:

Serial No. 128,682 Art Unit 3308

Whether the rejection of claims 1-36 as being based upon a defective reissue declaration, that declaration being the 5-17-95 declaration of Claude Ranoux and by reference thereto in such declaration, the 8-12-93 declaration of Robert J. Patch, under 35 USC 251 is proper? See also 37 CFR 1.175.

Appellant on page 2, line 25 - page 3, line 11 identified two "issues". However, Appellant on page 2, line 26 - page 3, line 6 included arguments concerning the merits of the first "issue", i.e. arguments concerning one of the bases for the first "issue". Still furthermore, Appellant at page 2, line L-publine 9 only identified the first "issue" with regard to only one bases therefor whereas, as set forth infra, there was more than one basis for the rejection. See (11) Ground of Rejection, infra, Finally, Appellant at page 2, line 25 - page 3, line 11 does not limit the "issues" to the rejection of the claims only based on the declarations of Claude Ranoux filed 5-17-95 and Robert J. Patch 8-12-93. declarations filed prior to the 5-17-95 Ranoux declaration, except Lfw the 8-12-93 Patch declaration referenced therein, are beyond the scope of this appeal, i.e. irrelevant as Appellant acquiesced to their insufficiently by the filing of the 5-17-95 declaration, i.e. the 5-17-95 Ranoux declaration is the declaration which was found defective and upon the rejection of the claims was 1 1 based in the FINAL rejection. The suitability of declarations filed after FINAL and not considered, as already initially noted in the (4) Status of Amendments After FINAL

section, supra, is a petitional rather than an appeable matter and are also beyond the scope of this appeal. Accordingly, any arguments regarding declarations other than the 5-17-95 Ranoux declaration, and thus 8-12-95 Patch declaration, will not be commented on by the Examiner as such comments would be improvident.

(7) Grouping of Claims

The rejection of claims 1-36 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) Claims Appealed

A substantially correct copy of appealed claim 12 appears on page 9 of the Appendix to the appellant's brief. The minor errors are as follows: claim 12 should be --12. Device according to claim 11, wherein said biodegradable means comprises temporary sealing means at the exit [area.] area defining means.

(9) Prior Art of Record

No prior art is relied upon by the examiner in the rejection of the claims under appeal.

(10) New Prior Art

No new prior art has been applied in this examiner's answer.

(3) Status of Claims

Claims 1-36 are rejected as being based upon a defective reissue declaration under 35 USC 251. See 37 CFR 1.175.

The declaration referred to is the 5-17-95 Ranoux declaration,

and thus the 8-12-93 Patch declaration referred to therein.

The reissue declaration of 5-17-95 is defective because it fails to particularly specify 1) the errors relied upon and 2) how the errors relied upon arose or occurred, as required under 37 CFR 1.175(a)(5). See page 2, lines 1-3 and 8-11 of the FINAL rejection, Paper No. 23.

- 1) See page 2, lines 4-7 of the FINAL rejection, Paper No. 23.
- 2) a. See page 2, lines 12-23 and page 4, line 23 page 5, line 1 of the FINAL rejection, Paper No. 23.
 - b. See page 2, line 24 page 4, line 13 and page 5, lines 2-10 of the FINAL rejection, Paper No. 23.
 - c. See page 4, lines 14-19 of the FINAL rejection, Paper No. 23.

(12) New Ground of Rejection

This examiner's answer contain REJECTION.

any NEW GROUND OF

(13) Response to argument

With regard to Appellant's remarks on page 3, line 15 - page 5, line 17 of the brief directed to Section 2)

a. of the Grounds of Rejection , supra, such remarks have been noted but are deemed nonpersuasive. The Examiner believes the Ground of Rejection set forth supra fully respond to Appellant's arguments. However, for clarity's sake, Examiner provides the following synopsis. Appellant believes error arose because the

PN2 20. 112

claims are limited to exclude a step which step has no bearing on the invention, see also the Ranoux declaration or affidavit filed 10 regarding the content of the August 12, 1993, Paper No. page 3, 5τς Ελυλημιαμή, specification, <u>not</u> the Ranoux Reissue Declaration and Power of It is Attorney filed May 12, 1993, Examiner's position that such step exclusion does not constitute "error" because it is not error to exclude that which is not part of the invention, i.e. the step has bearing on the invention in that the invention does not include such. For example, contrary to Appellant's arguments, col. 2, lines 7-9 does not limit the embryo transfer to that transfer from a container outside the body via a For further catheter to the interior of the uterine cavity only. example, Appellant interprets the teaching of col. 2, lines 7-9 to be that on page 4, lines 15-25, Yet this interpretation would thus also teach that the invention allows indirect transfer, i.e.by catheter, as long as the transfer is performed inside the mammal. Compare this to page 3, first full paragraph, last four lines of the 8-12-93, declaration or affidavit referred to supra.

The Examiner has found the claims, which define a broader form of the disclosed invention, i.e. no transfer from outside the Adminal to the interior of the uterine cavity, than the claims of the patent, allowable. However, the reissue declaration does not ascribe the error to be that they are entitled to the broadest claims drawn to such disclosed invention allowed by the prior art.

Regarding Appellant's arguments on page 5, last paragraph,

Serial No. 128,682 Art Unit 3308

with respect to all other reissue declarations and Power of Attorney other than the 5-17-95 Ranoux and 8-12-93 Patch declaration, see discussion in (6) Issues section, supra. As it regards sections 1)-2)c. in the Grounds of Rejection section with respect to the 5-17-95 Ranoux and 8-12-93 Patch declarations. Appellant has not specifically pointed out where the defects alleged are meet by the pertinent 5-17-95 declaration, e.g., where how the errors the relied upon, e.g., the amendments in the responses of June 16, 1994, February 7, 1995 and May 12, 1995, arose is set forth in the Patch 8-12-93 declaration.

The rejection of claims 1-36 as based upon a defective reissue declaration under 35 USC 251 is maintained as proper.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

K.Reichle/pw May 11, 1996

703-308-2617

FAX: 703-305-3590

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JOHN G. WEISS THERANY EXALITY II

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ROBERT J. PATCH YOUNG AND THOMPSON 745 SOUTH 23RD STREET ARLINGTON, VA 22202

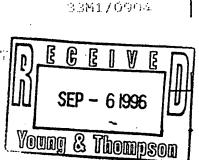


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SERIAL NUMBER FILING DATE FIRST NAMED APPLICANT ATTORNEY DOCKET NO.

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ART UNIT PAPER NUMBER
3308

DATE MAILED:

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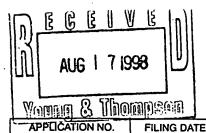
Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

The reply brief filed July 22, 1996 has been entered and considered but no further response by the examiner is deemed necessary. The application has been forwarded to the Board of Patent Appeals and Interferences for decision on the appeal.

It is noted that Paper No. 25, mailed 10/16/95 made it clear that the 10-2-95 declaration was not considered, i.e. not to be before Board of Appeals, and thus is not a new point of argument.

K. Reichle:lf August 28, 1996 703 308-2617 DAVID H. WILLSE PRIMARY EXAMINER GROUP 3300





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EXAMINER

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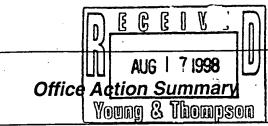
3735

DATE MAILED:

08/13/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks



Application No. | Applicant(s) | 28687 | Ranoux |

Examiner | Reichle | 3735-

(Today) & Substantial	
—The MAILING DATE of this communication appears on the cover she	et beneath the correspondence address—
Period for Response	つ
A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE MAILING DATE OF THIS COMMUNICATION.	
 Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, how from the mailing date of this communication. If the period for response specified above is less than thirty (30) days, a response within the simple of the period for response is specified above, such period shall, by default, expire SIX (6) MON Failure to respond within the set or extended period for response will, by statute, cause the approximation. 	statutory minimum of thirty (30) days will be considered timely. NTHS from the mailing date of this communication.
Status 5 21-96 41-78-97	14-1-97
Status \bowtie Responsive to communication(s) filed on $\frac{1}{7}$, $\frac{31-96}{5}$, $\frac{1}{1}$, 5 6 1 7
This action is FINAL.	
Since this application is in condition for allowance except for formal matters, paccordance with the practice under Ex parte Quayle, 1935 C.D. 1 1; 453 O.G.	prosecution as to the merits is closed in i. 213.
Disposition of Claims	
Claim(s)	is/are pending in the application.
Of the above claim(s)	is/are withdrawn from consideration.
□ Claim(s)	is/are allowed.
□ Claim(s) 1-3(.	is/are rejected.
☐ Claim(s)	is/are objected to.
☐ Claim(s)	
Application Papers	•
☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948	J
☐ The proposed drawing correction, filed on is ☐ approve	ved □ disapproved.
☐ The drawing(s) filed on is/are objected to by the Exami	iner.
The specification is objected to by the Examiner.	
☐ The oath or declaration is objected to by the Examiner.	
Priority under 35 U.S.C. § 119 (a)-(d)	
 □ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 □ All □ Some* □ None of the CERTIFIED copies of the priority docume □ received. □ received in Application No. (Series Code/Serial Number) □ received in this national stage application from the International Bureau (International Bureau) 	ents have been
*Certified copies not received:	•
Attachment(s)	
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s).	☐ Interview Summary, PTO-413
□ Notice of References Cited, PTO-892	□ Notice of Informal Patent Application, PTO-152
☐ Notice of Draftsperson's Patent Drawing Review, PTO-948	Other
Office Action Summary	<i>1</i>

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- 1. The FINAL rejection issued 8-21-95 is withdrawn due to changes to $37_{A}CAR$ 1.175 effective December 1, 1997, see discussion infra. An action on the merits follows:
- The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CAR-1.75(d)(1) and MEP: § 608.01(o). Correction of the following is required: Positive antecedent bases for steps a), c), d) and (e) of claim 1; a container means which is configured for accommodation mostly inside and lodgement in the uterine cavity and exit area defining means as claimed in claim 9, lines 4 et seq; and tube means sized for introduction into and lodgement in the uterine cavity as set forth in claim 23, lines 2-8; holding means as set forth on lines 10-12 of claim 23, and means for defining an exit area as set forth in claim 23, lines 13-19, should be defined. See following discussion.

While the disclosure describes direct transfer of at least one fertilized ovocyte into the uterine cavity from a container means, wholly within the uterine cavity, without removal of the container means from the uterine cavity and without removal of the fertilized ovocyte(s) from the uterine cavity between fertilization and direct transfer and exit area defining means for doing such (see col. 1, lines 53 et seq, col. 2, lines 1-9, and col. 3, lines 3-8 of the disclosure, i.e. Patentee sets forth that the prior art necessitates the replacement of embryos in the uterus and high manipulation of gametes leading to toxicity and embryo loss as well as setting forth that the instant invention overcomes these disadvantages by preventing embryo transfer from outside the mammal to the uterine cavity or that the container filled with the gametes once introduced into the uterine cavity requires no further intervention for implantation or embryos and that the container

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means resides wholly within the uterine cavity most of the time, except for those periods of time when the container means is being filled) removal of the container with the embryo inside it from the uterine cavity or a container means that is less than wholly placed in the uterine cavity when lodged therein, which is covered by the scope of the claims is not (i.e. removal of the container with the embryo inside it from the uterine cavity would constitute transfer of the embryo from outside the mammal to the uterine cavity or replacement of embryos in the uterus which appears to be contrary to the objects of the invention set forth in cols. 1-3 and would result in higher manipulation of the gametes). In other words, while Patentee has described a species of the broadly claimed invention, the generic invention or other species have not been described as part of the invention.

- 3. Claims 1-36 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for some of the claimed species, does not reasonably provide enablement for all of the claimed species. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. See discussion supra with regard to positive antecedent bases.
- 4. The disclosure is objected to because of the following informalities: At the very least, the description of the invention in col 1, line 1-col. 10, line 4 appears to be inconsistent with the claimed invention, see discussion of antecedent bases objection, supra.

Appropriate correction is required.

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The reissue oath/declaration filed with this application is defective because the error which 5. is relied upon to support the reissue application is not an error upon which a reissue can be based. See 37 CAR 1.175(a)(1) and M.E.P. § 1414.

Patentee identifies the error being corrected in all the declarations filed to date as the original patent to be partly inoperative by reason of the Patentee claiming more and less than the Patentee had the right to claim in the patent or, in other words that the claims were not narrow enough in some aspects and not broad enough in other aspects.

First it is noted that such does not state "wholly or partly inoperative or invalid".

Second, as discussed supra, since the scope or description of the invention in the original patent is limited to a direct transfer of at least one fertilized ovocyte into the uterine cavity from a container means, wholly within the uterine cavity, without removal of the container means from the uterine cavity and without the removal of the fertilized ovocyte(s) from the container means between fertilization and direct transfer and the structure for doing so, the claims as filed in the original specification were interpreted in light of such description. In the 9-21-90 Office Action it was indicated, see last paragraph thereof, that should such patentably distinguishable concept be explicitly incorporated in the claims, such claims would be allowable. Patentee responded on 12-21-90 with new claims, the process claims of which claimed providing access through an exit area without removal of the fertilized ovocytes from the uterine cavity. In the 4-17-91 Office Action it was again indicated such claims would be allowable if Patentee's concept as set forth in the last Office Action was set forth. Patentee responded on July 17, 1991 with claims of the scope as

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filed on 12-21-90 or broader. The Examiner contacted Patentee to suggest amendments which would be consistent with Patentee's concept, see Paper No. 11. The amendments were accepted. The reissue claims as now present in the application are of the same or broader scope than those claims that were canceled from the original application as interpreted in light of the scope of the disclosure.

As set forth in Ball Corporation v. U.S., 729 F.2d 1429, 221 USPQ 289 (Fed. Cir. 1989) while deliberate cancellation of a claim cannot ordinarily be considered error under section 251, where the deliberate cancellation of claims does not amount to an admission that the reissue claims were not patentable at the time the original claims were canceled, such cancellation is considered sufficient error or, to put it another way, error is established where there is no evidence that the Patentee intentionally omitted or abandoned the claimed subject matter. However, since evidence of the patentee's intent in canceling a claim presented is rare, courts have, as a practical necessity, drawn inferences from changes in claim scope when other reliable evidence of the Patentee's intent is not available. Id. Furthermore, the recapture rule bars the Patentee from acquiring, through reissue, claims that are the same as or of broader scope than those claims canceled from the original application. Thus, the applicability of the recapture rule and the sufficiency of error under section 251 turn, in the absence of other evidence of the Patentee's intent, on the similarity between reissue and canceled claims. <u>Id.</u>

As indicated supra, since the reissue claims are considered the same or broader in scope than those claims canceled from the original application as interpreted in light of the specification

Page 6

Serial Number: 08/128,682

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of the original application, the recapture rule comes into effect and thus the error which is relied upon to support the reissue application is not in fact an error upon which a reissue can be based or is insufficient.

6. Claims 1-36 are rejected as being based upon a defective reissue declaration under 35 U.S.C. 251 as set forth above. See 37 CAR 1.175.

The nature of the defect(s) in the declaration is set forth in the discussion above in this Office action.

7. Claims 1-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As discussed supra in paragraph 2, the subject matter which Applicant regards as the invention is not particularly pointed out or distinctly claimed since the claims don't claim the invention as set forth in paragraph 2, lines 9-20 thereof.

- 8. The claims, as interpreted in light of the specification, patentably distinguish over the prior art. It should be noted, however, that should the claims be more broadly interpreted that the claims might not patentably distinguish over the art, see, e.g., Lenck, '161 filed prior to the patent which includes a container which is less than entirely accommodated and lodged in the uterine cavity for affecting intra-uterine fertilization and embryonic transplantation.
- 9. Any inquiry concerning this communication should be directed to K. M. Reichle at telephone number (703) 308-2617.

Art Unit: 3735

R.M. Ruche KARIN REICHLE PATENT EXAMINER ART UNIT 328-3735

KMR

August 10, 1998

John G. Weiss

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Supervisory later a kaminer

Group 3700

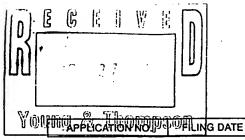


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APPLICANT IS	GIVEN ONE MONTH FRO	OM THE DATE OF THIS LETTER OR UN ACTION (WHICHEVER IS LONGER) WITI	r the reason(s) checked below and should be correcte TIL THE EXPIRATION OF THE PERIOD FOR HIN WHICH TO CORRECT THE INFORMALITY.
a. The amen	dment to claim(s)	tis accordingly held to be non-responsive.	A supplemental paper correcting the informal
h The namer	is unsigned. A duplicate t	paper or ratification, properly signed, is requ	aired.
c. The paper	r is signed by with a ratification, or a du	, who is plicate paper signed by a person of record, i	not of record. A ratification or a new power of s required.
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e. ⊠ Other T U. N. rr 37+	CERTIFIED	(1) 1 : 1 as specifice	ition are not in compliant
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No further exter	TO RUN	s approved by the Commissioner. 37 C.F.R.	1.136 (b)
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Young & Thompson





UNITED STALLS DEPARTMENT OF COMMERCE **Patent and Trademark Office**

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Washington, D.C. 20231

FIRST NAMED INVENTOR

ATTORNEY DOCKET NO.

06/128.682

ROBERT J. PATCH

YOUNG AND THOMPSON

745 SOUTH 23RD STREET ARLINGTON VA 12202

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REMOUNT

OM41/0426

EXAMINER

REICHLE, K

ART UNIT PAPER NUMBER

3761

DATE MAILED:

04/26/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

DEGET WED		
	Application No.	Applicant(s)
	Application No.	Karana N
Office Action Summary	Examiner	Group Art Unit
Young & Thompson	for the second	Group Art Unit
-The MAILING DATE of this communication appear	urs on the cover shee	t beneath the correspondence address
Period for Response A SHORTENED STATUTORY PERIOD FOR RESPONSE IS S	SET TO EVOIDE	MONTH/S) FROM THE
A SHORTENED STATUTORY PERIOD FOR RESPONSE IS S MAILING DATE OF THIS COMMUNICATION.	SET TO EXPINE	WONTHON THE
 Extensions of time may be available under the provisions of 37 CFR from the mailing date of this communication. If the period for response specified above is less than thirty (30) days If NO period for response is specified above, such period shall, by defeature to respond within the set or extended period for response will 	i, a response within the sta fault, expire SIX (6) MON , by stat u te, cause the app	atutory minimum of thirty (30) days will be considered timely THS from the mailing date of this communication. slication to become ABANDONED (35 U.S.C. § 133).
Status		784-77
Status A Responsive to communication(s) filed on	1,171	·
☐ This action is FINAL.		
Since this application is in condition for allowance excep accordance with the practice under Ex parte Quayle, 193	t for formal matters, p 35 C.D. 1 1; 453 O.G.	rosecution as to the merits is closed in 213.
Disposition of Claims		*
Ċ Claim(s)		is/are pending in the application.
Of the above claim(s)		is/are withdrawn from consideration.
☐ Claim(s)		is/are allowed.
☐ Claim(s) /		is/are rejected.
☐ Claim(s)	· · · · · · · · · · · · · · · · · · ·	is/are objected to.
☐ Claim(s)		are subject to restriction or election
Application Papers		requirement.
☐ See the attached Notice of Draftsperson's Patent Drawin	ng Review, PTO-948.	
☐ The proposed drawing correction, filed on	is 🗆 approve	ed [] disapproved.
The drawing(s) filed on is/are obje	cted to by the Examin	er.
The specification is objected to by the Examiner.		
The oath or declaration is objected to by the Examiner.		
Priority under 35 U.S.C. § 119 (a)-(d)		
 ☐ Acknowledgment is made of a claim for foreign priority to All ☐ Some* ☐ None of the CERTIFIED copies on a received. ☐ received in Application No. (Series Code/Serial Number of the CERTIFIED copies on a received in Application No. (Series Code/Serial Number of the Interest of the Interest	f the priority documen	ts have been
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☐ Information Disclosure Statement(s), PTO-1449, Paper ☐ Notice of References Cited, PTO-892		☐ Notice of Informal Patent Application, PTO-152
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U. S. Patent and Trademark Office PTO-326 (Rev. 3-97)

*U.S. GPO: 1997-417-381/62710

Part of Paper No.

- 1. The amendments filed 2-26-99 and 3-24-99 still do not comply with 37 CFR 1.121. The amendments to page 3, lines 18-24, line 2 thereof; claim 7, line 3; and claim 9, second to last line thereof do not comply. Patentee must in the next response, if any, bring these portions of the specification into compliance with 37 CFR 1.121. Failure to do so will result in a holding of nonresponsive with regard to such response.
- 2. The disclosure is objected to because of the following informalities:
- 1)At the very least, the description of the invention in col. 1, line 1-col. 10, line 4 appears to be inconsistent with the claimed invention, see discussion of antecedent bases objection, infra. It is noted that the portions referred to include the Summary of the Invention section which is to describe the invention in the same scope as that claimed.
 - 2) In the amendment to page 3, lines 18-24, line 2 thereof, "a" should be deleted.
- 3) In the amendment to page 7, lines 57-58, line 2 thereof, the line appears to be missing a word, e.g. after "cavity", should --and-- be inserted?

Appropriate correction is required.

3. The amendment filed March 24, 1999 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the amendment to page 10, lines 38-59, lines 12-16 thereof.

Applicant is required to cancel the new matter in the reply to this Office action.

Art Unit: 3735

Patentee now sets forth that the container means, i.e. collectively the container and the holding device, are mostly accommodated in the uterus, i.e. the uterine cavity and the neck of the uterus, and lodged in the uterine cavity. First, "mostly" according to its common and usual definition, i.e. dictionary definition, is "For the greatest part; almost entirely." In other words more than 50% but less than 100%. While the originally filed specification teaches the container, as compared to the container means, which is entirely accommodated in the uterus and lodged in the uterine cavity in Figure 1f, this is not the embodiment being described on page 10. Figures 7 and 8 also show a container which is mostly accommodated in the uterus and lodged in the uterine cavity but the portion of the holding device and container means shown in the Figure does not support the full scope of the amendment, e.g. where is it taught that just less than 100% of the container means is accommodated by the uterus?

4. Claims 23-36 and 39 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. See discussion in preceding paragraph. Even though no actual amendment has been made to the claims, the amendment to the specification indirectly affects the claim because the interpretation of claim 23, lines 11-13 and corresponding language in claim 39 in light of the specification would encompass a tube and holding means combination which is more than 50% but less 100% accommodated by the uterus. Persons skilled in the art at the time the application was filed would not have recognized the description of this limitation in

the disclosure of the application as filed because, see, e.g, Figures 1f or 7-8, the invention as disclosed is described as having a portion greater than, e.g, than an insignificant portion, not accommodated by the uterus

5. Claims 1-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Again, with regard to all the claims, the subject matter deemed essential for the invention to enable fertilization and transplantation, see discussion in paragraph 6, has not been set forth.

In regard to claim 9, a positive structural antecedent basis "said container means" (line 5) should be defined. In regard to claim 10, positive structural antecedent bases for "means defining an exit area" and "container means" should be defined. In regard to claim 16, a positive structural antecedent basis for "the container means" should be defined. In regard to claim 23, the description on line 4 is inaccurate, i.e. "uterine cavity" should be --uterus--. In regard to claim 29, a positive structural antecedent basis for "tube means" should be defined. In regard to claims 30, 31 and 35, "one of the ends" should be --ones of the ends to be consistent and accurate, see, e.g., claim 29.

6. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: positive antecedent bases for step (e) of claim 1 and 37, and thereby claims 2-8; lines 12 et seq. of claim 9 and corresponding language in claim 38, and thereby claims 10-22;

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and lines 13-20 of claim 23 and corresponding language in claim 39, and thereby claims 24-36 should be defined. See following discussion and response to Patentee's arguments infra.

While the disclosure describes direct transfer of at least one fertilized ovocyte into the uterine cavity from a container, wholly or at least mostly accommodated in the uterus and lodged in the uterine cavity, without removal of the container from the uterine cavity and without removal of the fertilized ovocyte(s) from the uterine cavity between fertilization and direct transfer and an exit area for doing such(see col. 1, line 53 -col. 2, line 9 and col. 3, lines 3-8 and Figures 1f and 7-8 of the disclosure, i.e. Patentee sets forth that the prior art necessitates the replacement of the embryos in the uterus and results in high manipulation of the gametes leading to toxicity and embryo loss as well as setting forth that the instant invention overcomes these disadvantages by preventing embryo transfer from outside the mammal to the uterine cavity or that the container once introduced into the uterine cavity requires no further intervention for implantation of embryos and that the container resides wholly or is at least mostly accommodated in the uterus and lodged within the uterine cavity, except for those periods of time when the container is being filled), removal of the container with the embryo inside it from the uterine cavity or a container that is less than wholly placed in the uterine cavity or a container which is more than or less than mostly accommodated in the uterus and lodged in the uterine cavity when lodged therein, which is covered by the scope of the claims is not(i.e. removal of the container with the embryo inside it from the uterine cavity or replacement of embryos in the uterus appears to be contrary to the objects of the invention set forth in cols. 1-3 and would result in higher

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manipulation of the gametes). In other words, while Patentee has described a species of the broadly claimed invention, the generic invention or other species have not been described as part of the invention.

- 7. Claims 1-19 are rejected under 35 U.S.C. †12, first paragraph, because the specification, while being enabling for some of the claimed embodiments, does not reasonably provide enablement for all the claimed embodiments. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. See discussion supra with regard to positive antecedent bases and response to Patentee's arguments, infra.
- 8. The claims, as interpreted in light of the specification, patently distinguish over the prior art.
- 9. The reissue oath/declaration filed with this application is defective because it fails to contain a statement that all errors which are being corrected in the reissue application up to the time of filing of the oath/declaration arose without any deceptive intention on the part of the applicant. See 37 CFR 1.175 and MPEP § 1414.
- 10. The reissue oath/declaration filed with this application is defective (see 37 CFR 1.175 and MPEP § 1414) because of the following:
- 11. It does not state that the person making the oath or declaration has reviewed and understands the contents of the specification, including the claims, as amended by any amendment specifically referred to in the oath or declaration.

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12. Claims 1-39 are rejected as being based upon a defective reissue declaration under 35 U.S.C. 251 as set forth above. See 37 CFR 1.175.

The nature of the defect(s) in the declaration is set forth in the discussion above in this Office action.

- 13. Patentee's attention is further directed to MPEP 1414.01(July 1998), i.e. depending on the errors corrected in the reissue prior to allowance, if any, and whether such was identified in the original declaration, a supplemental declaration might have to be submitted.
- 14. Patentee's remarks on pages 10-11, first, second and fifth full paragraphs of section 1. are noted. Patentee's remarks in the third and fourth full paragraphs of section 1. have been noted. It is the Examiner's position that a simple comparison of the last Office Action to the issues set forth in the Examiners Answer indicates or explains the effect of the rule changes on the rejections outstanding in the Examiners Answer. Furthermore, Examiner can not find any requirement to explain or indicate in a manner than already set forth the effects of such rule changes. Patentee is requested to set forth where such requirement is set forth if such line of argument is continued.
- Patentee's remarks on page 11, line 3-page 19, line 4 have been noted but are deemed moot in that such issues have not been reraised.
- 16. Patentee's remarks on page 19, lines 5-13, page 22, last full paragraph and page 23, lines 1-4 have been noted. Attention is directed to paragraphs 3-7 supra.
- 17. Patentee's remarks on page 19, line 14-page 22, line 14 have been considered but are deemed nonpersuasive for the reasons set forth in paragraphs 3-7 supra. It is noted that Patentee

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does not specifically point out how their position is reconcilable with col. 2, lines 7-9 of the patent(Note: "This method..." is set forth not "a embodiment" or some other term(s) to indicate optionality. It is still further noted that such objective does not limit itself to transfer by means of catheter from outside the mammal to the interior of the <u>uterine cavity</u>. Attention is also invited to page 24, lines 6-7 and 9-11. Attention is still further invited to the language of claims 1-36 which does not preclude manipulation or removal of the embryos from the container between fertilization and direct transfer. Furthermore, there is no evidence of record that manipulation or removal of the container from the uterine cavity between fertilization and transfer does not cause manipulation of the embryos nor additional risk of toxicity. Thus, in conclusion, Patentee's statements in the second full paragraph on page 23 are deemed nonpersuasive.

- 18. Patentee's remarks in sections 3 and 4 have been considered but are deemed nonpersuasive in light of the discussion in paragraphs 3-7 and 17 supra.
- 19. Patentee's remarks on page 25 lines 3-5 and page 27, line 1-page 28, line 5 have been considered and are well taken with regard to the lack of applied art. Therefore, the issue of defectiveness with regard to the declaration for this reason have been withdrawn. However, it is noted that the declaration is still considered defective for other reasons discussed supra. The remainder of Patentee's remarks in section 5. are not well taken in light of the record. For example, since a 312 amendment is not an amendment of right, no claims were reinstated as compared to proposed. For another example, although the amendment was filed 9-11-91, the amendment was not received in the file until 1-6-92 and acted on by Examiner by 1-7-92. For a

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third example, there is nothing of record which indicates that Patentee was precluded from

exercising options, e.g. filing a continuation, other than paying the issue fee and allowing issuance

of the patent.

Patentee's remarks in section 7. have been considered but are deemed nonpersuasive in 20.

light of the discussion in paragraphs 3-7 and 17-18, supra.

Patentee's remarks in section 8. have been noted. It is pointed out that such remarks 21.

appear to be inconsistent with some of the Patentee's other remarks with respect to the invention.

For example, Patentee points out that the Lenck container is less than entirely accommodated and

lodged in the uterine cavity. Yet, Patentee previously argued that the container of the invention

does not require such. Patentee further states in one sentence that only the mouth of the Lenck

container is located inside the uterine cavity, i.e. lodged therein, but two sentences later argues the

container is not lodged in the uterine cavity. Finally, what claim language precludes surgery and

recovery as a method of introduction?

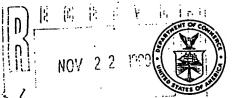
The remainder of Patentee's remarks have been noted. 22.

Any inquiry concerning this communication should be directed to K.M. Reichle at 23.

telephone number (703) 308-2617

April 20, 1999

John G. Weiss Supervisory Patent Examiner Group 3700



UNITED STATES DEPARTMENT OF COMMERCE Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS

08/128,68 6 Washington, D.C. 20231 ATTORNEY DOCKET NO. FIRST NAMED APPLICANT FILING DATE SERIAL NUMBER 1997 307975 DOMENUX 08/128,682**EXAMINER** QM1271116 ROBERT J. PATCH PAPER NUMBER **ART UNIT** YOUNG AND THOMPSON 745 SOUTH 23KD STREET ARLINGTON VA 22202 DATE MAILED: 11/16/99 This is a communication from the examiner in charge of your application. COMMISSIONER OF PATENTS AND TRADEMARKS is informal/non-responsive for the reason(s) checked below and should be corrected. 1. The communication filed APPLICANT IS GIVEN ONE MONTH FROM THE DATE OF THIS LETTER OR UNTIL THE EXPIRATION OF THE PERIOD FOR RESPONSE SET IN THE LAST OFFICE ACTION (WHICHEVER IS LONGER) WITHIN WHICH TO CORRECT THE INFORMALITY. a. The amendment to claim(s) 1.56.000 to last line, filed 102(-91, fails to comply with the provisions of 37 C.F.R. 1.121 and is accordingly held to be non-responsive. A supplemental paper correcting the informal portions and complying with the rule is required. b. L. The paper is unsigned. A duplicate paper or ratification, properly signed, is required. , who is not of record. A ratification or a new power of c. The paper is signed by attorney with a ratification, or a duplicate paper signed by a person of record, is required. d. The communication is presented on paper which will not provide a permanent copy. A permanent copy, or a request that a permanent copy be made by the Office at applicant's expense, is required, see M.P.E.P. 714.07. c. Other In accordance with applicant's request, THE PERIOD FOR RESPONSE FROM THE OFFICE ACTION DATED IS EXTENDED TO RUN _ MONTH(S). No further extension will be granted unless approved by the Commissioner, 37 C.F.R. 1.136 (b) 3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119 which papers have been made of record in the file.

4. Nother II the file of the fi : Claims .

Karin M. Reichle Petent Examiner

EXHIBIT G

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Claude RANOUX et al Patent No. 5,084,004 (Serial No. 07/449,942) Expired January 28, 1996 (Filed December 29, 1989 Issued January 28, 1992

PROCESS FOR INTRA-UTERINE FERTILIZATION IN MAMMALS AND DEVICE FOR IMPLEMENTATION THEREOF

DECLARATION OF HERBERT A. LEWITTER

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

- I, the undersigned Herbert A. Lewitter, declare as follows:
- 1. I am a registered patent attorney and a member of Cabinet Bonnet-Thirion, ,12 Avenue de la Grande-Armée, 75017 Paris, France, a French firm of Industrial Property Attorneys (conseils en propriété industrielle), and have been with the firm since February 1970.
- 2. Our firm represents Dr. Claude Ranoux in patent malters. I drafted the above-identified patent application under instructions of Dr. Claude Ranoux and it was filed and prosecuted through our U. S. associates, Young & Thompson, who are the attorneys of record in the reissue application and in the original application.

- 3. I received the Notice of Allowability along with the Examiner's Amendment. I realized that the Examiner's Amendment contained an unduly limiting amendment to claims 28, 50 and 64 and informed Mr. Robert Patch of the error by letter of August 30, 1991 and then proposed an amendment to correct the error by letter of September 3, 1991, asking Mr. Patch to proceed with a Rule 312 Amendment.
- 4. To the best of my knowledge, at no time did I, anyone in our firm or the inventor Dr Claude Ranoux instruct Young & Thompson to pay the issue fee.
- 5. The amendment was not acted upon until January 14, 1992. Once I learned that the Rule 312 Amendment had been refused, which had the effect of reinstating the Examiner's Amendment, I attempted to instruct Mr. Patch to proceed with a continuation application which failed, as the application issued on January 28, 1992 before anything could be done.
- 6. I immediately instructed Mr. Patch to proceed with the preparation of a reissue application so as to correct the erroneous language in the claims.
- 7. At the time the Ranoux patent No. 5,084,004 issued, Young & Thompson would send us the letters patent document along with a cover letter indicating the dates on which the maintenance fees are to be paid. However, because the letters patent had to be surrendered to the U.S. Patent and Trademark Office in the reissue application, Young & Thompson did not forwarded it to our firm, nor did they send us the usual accompanying letter.
- 8. I am fully familiar with procedures which have been used in our firm for renewal payments and maintenance fees, in France, the United States and other countries.

- In great majority of countries where the annuity fees are due on the anniversary date of the application, the application is docketed on our computerized reminder and payment system at the time of filing.
- 10.In other countries, namely the United States of America, where maintenance fee due dates are calculated from the date the patent issues, the case is not put on our computerized reminder and payment system until after the patent issues.
- 11. In accordance with the proceedures used in our firm for the entry of U.S. patents on our computerized reminder and payment system, the letters patent is presented to the attorney in charge of the prosecution, which in this case was me, and after reviewing it he/she sends it on to our annuities department where it is docketed on our computerized renewal system, bearing in mind the specific instructions of the (foreign) attorney of record. In this case, as noted above, no letters patent was received and Ranoux patent No. 5,084,004 was never entered on our firm's computerized or backup manual patent renewal system.
- 12. Although the reissue application has been prosecuted and a continuation filed, we had received no notice from Young & Thompson concerning the maintenance fees due in this matter, until Eric Jensen's letter of December 21, 1999 advising us that the Examiner informed him that the maintenance fees due on this patent had not been paid. We immediately instructed him to proceed with Petition to Accept Unavoidably Delayed Payment.

And I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

ate: [1 / 18, 2000

Hertert A. Lewitter